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Medical Focus - Avian Flu Essentials

April 28, 2006

Dear Colleague:

In the twenty-third letter of the Avian Flu Essentials series, I would like to present the findings from the U.S. Food and Drug Administration and the Pediatric Advisory Committee on the safety of Tamiflu in children.

In November 2005, concern was raised over the deaths of twelve Japanese children and whether these were associated with their intake of the drug Tamiflu. Some cases of hallucination and delirium had also been reported. Upon further investigation, the Pediatric Advisory Committee (PAC) has found no direct link between the drug and the deaths. Comorbid conditions and confounding variables were present in these cases. In addition, the committee has not observed similar childhood neuropsychiatric adverse events in the U.S. A limited number of skin reactions related to the use of Tamiflu are currently under additional review.

Since the reports were mainly from Japan, the PAC explored whether the discrepancies in manifested adverse events were due to a difference between U.S. and Japanese populations. The main factors that have been attributed are discussed below.

The flu season in Japan was particularly active in 2004-2005 with twice as many cases compared to the U.S. In addition, the neurological complications were manifested at the same time as flu complications, which can be caused by the viral infection itself, such as febrile convulsions (due to high body temperature).

Furthermore, Japan conducts postmarketing safety studies following the approval of new drugs and contacts providers directly to urge reports. Therefore, an active influenza season could have resulted in more reports. However, analysis of this aggregate data for Tamiflu-associated events should take into consideration comorbid conditions and the chronological appearance of symptoms.

Finally, not a single death has been linked to Tamiflu in the United States. The FDA continues to support that Tamiflu is safe in children and will continue to monitor pediatric adverse events during the next two years. An article on the reverse of this letter shows that Tamiflu has also been approved for prophylaxis in children.

Sincerely,

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Excerpt from an FDA release, *FDA Approves Tamiflu for Prevention of Influenza in Children Under Age 12*, December 22, 2005:

On December 21, 2005, the U.S. Food & Drug Administration (FDA) approved the use of Tamiflu (oseltamivir phosphate) for prevention (prophylaxis) of seasonal influenza ("flu") in children 1 to 12 years of age who had close contact with an infected individual. This is the first drug approved for prevention of both influenza A and B in pediatric patients.

Tamiflu is an oral anti-viral drug previously approved by FDA for both the prevention and treatment of influenza in adolescents 13 years and older, and in adults. Tamiflu also is approved for treatment of influenza in pediatric patients older than 1 year of age.

A study of the spread of flu in households involving over 1100 people included 222 children 1 to 12 years of age. When someone in the household was diagnosed with seasonal flu, other family members received either Tamiflu once a day for 10 days or no Tamiflu at all unless they became ill. The rate of children developing fever and other symptoms confirmed to be flu was reduced from 17% in the group receiving no preventative treatment to 3% in the group that received Tamiflu as a preventative measure. The benefit in children mirrored the benefit seen in older individuals in this and earlier studies. The effective use of Tamiflu to prevent influenza in immunocompromised patients has not been established.

In the studies, side effects from Tamiflu, when taken for prevention, were similar to those from patients who took the drug for treatment. The most common side effects were nausea, vomiting, headache and fatigue. Vomiting was reported more frequently in people receiving the twice daily treatment dose compared to once daily prophylaxis. In the current study, children reported higher rates of vomiting than adults but this was observed to be dose-related. Although no new side effects occurred in these studies, FDA has requested additional postmarket study data from the drug maker to support the long term safety of the drug.

A comprehensive review of post-marketing safety reports for Tamiflu indicated rare reports of severe rash and allergic-type skin reactions that may be drug-related. As was discussed at the FDA Pediatric Advisory Committee, on November 18, 2005, FDA required that new safety language regarding serious skin/hypersensitivity reactions be added to the Tamiflu product label. Patients should be cautioned to stop taking Tamiflu and contact their health care providers if they develop a severe rash or allergic symptoms.

Tamiflu is not a substitute for the flu vaccine. Patients should continue receiving an annual flu vaccination according to guidelines on immunization practices.

Tamiflu is manufactured and distributed by Roche Pharmaceuticals, Inc. of Nutley, N.J.